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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09.633,541	08.07.2000	Marcel Loetscher	2225.1001-010	3846

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/08/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/633,541

Applicant(s)

LOETSCHER ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 30-49, 51, 52 and 60-105 is/are pending in the application.
- 4a) Of the above claim(s) 49, 51 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 30-48, 60-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Formal Matters

1. Claims 30, 34, 37, 38, 40-42, 44, 46, 48, 60-75, 81 and 85-92 were amended, and new claims 93-105 were added in Paper No. 8, 12/27/2001.

2. Claims 49, 51-52 stand withdrawn from further consideration by the Examiner pursuant to 37 CFR 1.142(b). Claims 30-48, 60-105 are under consideration.

Double Patenting

3. Claims 75-79, 81-82, 84 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-34 of U.S. Patent No. 6,140,064. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons of record set forth in Paper No. 7, 5/22/2001.

Applicant argues that they will consider filing a Terminal Disclaimer when the claims are indicated as being allowable, however, this rejection will not be withdrawn until a Terminal Disclaimer over U.S. Patent No. 6,140,064 is received.

Claim Rejections - 35 USC § 112 first paragraph

4. Claims 30-52, 60-74 and 85-92 stand rejected, and new claims 93-105 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

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The rejection argues that while the specification and the art provides adequate written description for a method of detecting or identifying an agent which binds a human CXCR3 with an amino acid sequence as set forth in SEQ ID NO: 2, the specification fails to adequately describe a method of detecting or identifying an agent which binds a mammalian CXCR3. The skilled artisan cannot envision all the possible mammalian CXCR3 proteins, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Only a method of detecting or identifying an agent which binds a human CXCR3 with an amino acid sequence as set forth in SEQ ID NO: 2 meets the written description provision of 35 U.S.C. §112, first paragraph.

Applicant argues that the specification contains an adequate written description of the claimed subject matter because the claims contain a function (binding IP-10 and Mig) and a structural limitation (80-90% homology, encoded by a nucleic acid which hybridizes to SEQ ID NO: 1). However, as Applicant points out, in Lilly the court held that one of two elements may satisfy a genus of cDNAs, i.e. i) a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or; ii) a recitation of structural features common to members of the genus, which features constitute a substantial protein of the genus. University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997). In the instant case, the first element is not met because only a cDNA encoding SEQ ID NO: 2 is disclosed. The second element requires structural features common to members of the genus, however, in the instant disclosure, insufficient guidance is provided as to which are the critical residues which are necessary for the claimed protein function of binding IP-10 or Mig. Even at a 90% homology, SEQ ID NO: 2 is 368 amino acids long, thus mutations could be introduced at up to ca. 37 amino

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acids, and each possible mutation is chosen from 20 possible amino acids. These claims encompass a very large number of possible members of the genus (37^{20} possible members, not including deletion mutants). Applicant points to the Written Description guidelines, which include an example of a claim having written description which is directed to a protein and variants thereof that are at least 95% identical, with a specific catalytic function. If the claims were amended to meet similar structural limitations, the rejection might be reconsidered.

5. Claims 30-52, 60-74 stand rejected, and amended and new claims 85-105 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting or identifying an agent which binds a human CXCR3 with an amino acid sequence as set forth in SEQ ID NO: 2, does not reasonably provide enablement for a method of detecting or identifying an agent which binds a CXCR3 protein variant having at least 80 or 90% amino acid sequence identity to SEQ ID NO: 2, or a method of detecting or identifying an agent which binds an CXCR3 protein variant encoded by a nucleic acid sequence with 75% identity with SEQ ID NO: 1, or are encoded by a nucleic acid which hybridizes to SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The rejection argues that the claim are overly broad in the recitation of "at least about 80 or 90% identity" since no guidance is provided as to which of the myriad of polypeptide species encompassed by the claim will retain the characteristics of a CXCR3 protein. In the specification (page 14 line 23 to page 15, line 14), Applicants disclose that variants of the polypeptide includes deletions substitutions and variants, without disclosing any actual or

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prophetic examples on expected performance parameters of any of the possible muteins of CXCR3 protein. The rejection cited Mikayama et al. and Voet et al. to demonstrate the unpredictability of the protein art. There is no guidance provided in the specification as to how one of ordinary skill in the art would practice a method of detecting or identifying an agent which binds a CXCR3 protein variant having at least 80 or 90% amino acid sequence identity to SEQ ID NO: 2, or a method of detecting or identifying an agent which binds an CXCR3 protein variant encoded by a nucleic acid sequence with 75% identity with SEQ ID NO: 1 other than those exemplified in the specification

Applicant argues that it would require routine experimentation to follow the guidelines set forth in the specification to prepare CXCR3 proteins or variants. However, as set forth *supra*, even at a 90% homology, SEQ ID NO: 2 is 368 amino acids long, thus mutations could be introduced at up to ca. 37 amino acids, and each possible mutation is chosen from 20 possible amino acids. These claims encompass a very large number of possible members of the genus (37^{20} possible members, not including deletion mutants). Additionally, there is insufficient guidance provided to indicate which amino acid residues are necessary for the CXCR3 function of binding IP-10 and Mig. Given the large number of possible species encompassed by the claims, and the insufficient guidance provided in the specification as to the critical residues necessary for protein function, and the evidence provided in the Mikayama et al. and Voet et al. references showing the unpredictability of the protein art, it would have required undue experimentation for one of skill in the art to practice the claimed invention.

Conclusion

6. No claim is allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
February 28, 2001


DAVID S. ROMEO
PRIMARY EXAMINER